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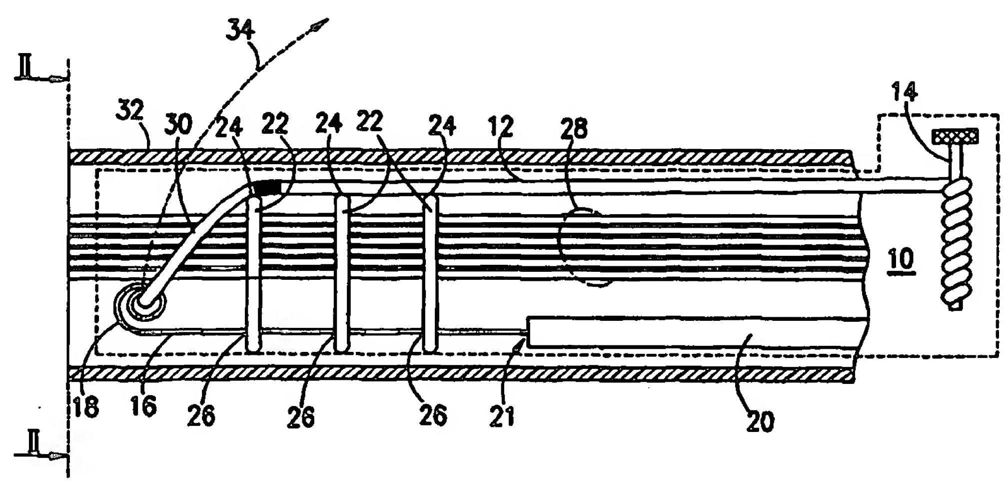


(57) Abstract

An elongate probe (32) having a longitudinal axis and a distal tip (80), and including at least one deflection mechanism (10), which includes an elastic flexible member (16, 86), having distal and proximal ends and having a predetermined bending stiffness. The flexible member is fixed within the probe generally parallel to the longitudinal axis thereof. The probe further includes a pull wire (12, 84) having a distal end coupled to the distal end of the flexible member, and a proximal end that is tensioned longitudinally to deflect the probe.

# DEFLECTABLE CATHETER

## FIELD OF THE INVENTION

The present invention relates generally to the field of catheters, and specifically to compact deflection mechanisms in catheters.

## BACKGROUND OF THE INVENTION

Numerous tip deflection mechanisms for catheters are known in the art. For example, PCT publication WO 96/05768, the disclosure of which is incorporated herein by reference, describes a two-cable tip deflection mechanism for a catheter. In this mechanism, the tip of the catheter comprises a relatively flexible flat portion, which is slit along a part of its length to form two portions. These two portions are connected at a first end, which is attached to the tip of the catheter. A cable is connected to each of the portions at a second end thereof. Thus, pulling one of the two cables bends the flexible portion toward the side on which that cable lies, and so urges the distal tip of the catheter toward that side.

U.S. patents, 4,886,067, 4,921,482, 4,934,340, 5,487,757, 5,531,686, 5,555,883, 5,571085 and 5,588,964, the disclosures of which are incorporated herein by reference, all describe tip deflection mechanisms for catheters.

## SUMMARY OF THE INVENTION

It is an object of some aspects of the present invention to provide a low profile tip deflection mechanism suitable for bending a catheter with a large central lumen or a large central obstruction, such as wiring.

It is another object of some aspects of the invention to provide a deflection mechanism which is simple to implement, and allows accurate control of the degree of bending, and maintaining and reproducing the applied bend.

In addition, some aspects of the present invention provide a deflection mechanism whose operation is substantially direct and has a minimum backlash.

Still another object of some aspects of the present invention is to allow for a bending site for the deflection mechanism which is distant from the tip of the catheter.

Another object of some aspects of the present invention is to provide a deflection mechanism characterized by a re-locatable bending site. In addition, further aspects of the present invention provide an adjustable deflection radius.

Another object of some aspects of the present invention is to provide a deflection mechanism capable of bending a catheter in more than one direction.

In accordance with some preferred embodiments of the present invention, a deflectable catheter comprises a tip deflection mechanism which includes a pull wire, an elastic flexible member and a stiffener. The flexible member, stiffener and pull wire preferably lie along the longitudinal axis of the catheter. Preferably, the stiffener and flexible member are on one side of the catheter, while the pull wire is preferably located on the diametrically opposed side of the catheter. Beyond the bending site, toward the distal end of the catheter, the pull wire is connected to the flexible member. When the wire is pulled, the flexible member bends toward the pull wire, causing the catheter to bend in the same direction. The stiffener's distal end serves as an anchor that causes the flexible member to bend at the bending site. Preferably, the flexible member has a preferred bending plane and a predetermined rest position and bending stiffness. Bending the flexible member gives rise to an elastic return force, so that when the pull wire is released, the flexible member bends back into its rest position and the catheter is straightened.

In other preferred embodiments of the present invention, the pull wire and flexible member are fixed in generally diametrically opposed positions to an inner surface of an outer wall of the catheter at the catheter's distal end. The flexible member is preferably connected proximally to a stiffener. More preferably, the stiffener comprises a resilient rod, running longitudinally along the length of the catheter, and a portion of the rod in a vicinity of the distal end of the catheter is flattened to reduce its resistance to bending in a transverse direction, thereby forming the flexible member. When the wire is pulled, the catheter bends toward the wire, as described above. Preferably, over at least a portion of the length of the catheter, the pull wire is contained in a sheath fixed to the stiffener, to prevent tangling and/or snags of the wire.

In some aspects of the invention, the flexible member has a curved element at its distal end. The curved element is preferably a portion of the flexible member. The pull wire and the flexible member are preferably connected by having the pull wire threaded through the curved element. The curved element is shaped as a spiral, loop, hook or any other shape which keeps the pull wire connected to the flexible member. Alternatively, or additionally, the pull wire and the flexible member are connected by an adhesive or are welded together.

In some embodiments of the present invention, the catheter wall also has a certain stiffness, preferably stiffer than the flexible member. Thus, the stiffener and the wall of the catheter define together the bending site.

In a preferred embodiment of the invention, the pull wire may lie anywhere within the catheter, except in regions which are occupied, for example, by wiring. To provide the pull wire

with leverage over the flexible member, where the pull wire runs parallel the flexible member, the pull wire is preferably separated from the flexible member by one or more spacers. The spacers prevent radial movement of both the pull wire and the flexible member and are preferably rings of rigid material having two attachments at diametrically opposite locations on their perimeter. One side of each spacer is connected to the flexible member and the opposite side is connected to the pull wire. Thus, the pull wire and the flexible member are substantially constrained to opposite sides of the catheter. It should be noted that when the catheter has a large lumen or core, e.g., containing wiring or other interior equipment, the spacers encircle the lumen or core.

A further variation of the present invention involves having the proximal end of the pull wire wound round a control spindle. When the spindle is rotated in a winding direction, the wire is pulled and the deflection of the catheter tip is increased. When the spindle is rotated in the opposite direction, the pull wire is released and the deflection of the catheter tip is reduced due to the elastic return force provided by the flexible member. The control spindle preferably has a friction, ratchet or other mechanism for automatically maintaining its position and, thereby, the position of the flexible member. In addition, in some preferred embodiments of the invention, the control spindle incorporates a turn-counting mechanism which allows repeatable applying of substantially any degree of bending to a pre-defined precision.

Ordinarily the bending site is near the tip of the catheter. However, in some embodiments of the invention the catheter bends at a pre-determined site, not necessarily near its tip. In one embodiment, a flexible member is fixed to the catheter wall at the pre-determined bending site, and the catheter wall is stiff everywhere except at the predetermined site. Therefore the catheter bends essentially only at the pre-determined site, when the flexible member is bent by the pull wire.

In further embodiments of the invention the bending site is re-locatable by the user. In a preferred embodiment of the invention, a deflection mechanism comprising, as described above, a stiffener, a flexible member, a pull wire and possibly spacers, lies along the length of the catheter. The bending site is preferably re-located by sliding the stiffener along the length of the catheter and bringing the distal end of the stiffener to the chosen bending site. The portion of the catheter wall which may be distal to re-locatable bending sites is, preferably, sufficiently stiff such that the portion of the catheter distal to the deflection mechanism will take up a position according to the bend applied at the bending site, although the catheter has no stiffener distal to

the bending site. In a preferred embodiment of the invention, the catheter wall has a certain degree of stiffness along the entire length of the catheter.

In another embodiment, allowing for a re-locatable bending site, a stiffener and a flexible member may be moved independently of one another. Curvature of the bend depends on the length of that portion of the flexible member which is distal to the distal end of the stiffener. The catheter wall is, preferably, stiff enough along its entire length so that the portion of the catheter distal to the deflection mechanism takes up a position according to the applied bend. The bending site is re-located by moving the flexible member and the stiffener, and the curvature of the bend is controlled by adjusting the relative positions of their distal ends.

In a further embodiment of the present invention the flexible member is located within the stiffener, and the flexible member may be moved independently within the stiffener. Thus the curvature of the bend is controllable, while the deflection mechanism takes up minimal space within the catheter.

In a further preferred embodiment of the invention, the catheter has a rest position which is not straight. Preferably, this is achieved by having an elastic flexible member, having a preferred bending plane formed so as to have an inherently bent configuration. In one preferred embodiment of the invention, the flexible member is used to bias the catheter along a direction in the preferred bend plane as if the pull wire had been pulled ('inwardly biased'). In another preferred embodiment, the bias is in the opposite direction ('outwardly biased') thereby providing for bending to either side of a straight position.

In another preferred embodiment of the invention, the deflection mechanism can bend the catheter in more than one direction. Preferably, two complete sets of pull wires, stiffeners, flexible members, and spacers are mounted at right angles with respect to one another, thus forming a double orthogonal mechanism within the catheter. Preferably, the stiffeners are circular in cross section and do not have a preferred bending plane. Rather, the bending plane is determined based on the amount the pull wires are shortened.

In yet a further preferred embodiment of the invention, inwardly or outwardly biased flexible members are incorporated into a double orthogonal mechanism. In particular, the use of two outwardly biased flexible members enables bending the catheter in any direction relative to its central axis.

In another preferred embodiment of the invention, the double orthogonal mechanism has only one, tube shaped, stiffener to which the flexible members are connected.

Another preferred embodiment of the invention provides the catheter with more than one bending direction. In this embodiment, two pull wires are threaded through a loop or other curved element situated at the distal end of a single flexible member, forming a dual pull wire mechanism. Preferably, two sets of spacers separate the pull wires from the flexible member in a manner that causes the pull wires to pull the loop or other curved element in different planes. Consequently, the total tension in the pull wires determines the degree of bending of the catheter, and the bending plane of the catheter is determined based on the ratio of the tensions of the pull wires.

In yet another preferred embodiment of the invention, an outwardly biased flexible member is incorporated into a dual pull wire mechanism to enable bending of the catheter in any direction relative to its central axis.

There is therefore provided, in accordance with a preferred embodiment of the present invention, an elongate probe having a longitudinal axis and a distal tip, and including at least one deflection mechanism, which includes:

an elastic flexible member, having distal and proximal ends and having a predetermined bending stiffness, wherein the flexible member is fixed within the probe generally parallel to the longitudinal axis thereof; and

a pull wire having a distal end coupled to the distal end of the flexible member, and a proximal end that is tensioned longitudinally to deflect the probe.

Preferably, the distal end of the pull wire is fixed to the distal end of the flexible member.

In a preferred embodiment of the present invention, the flexible member is movable longitudinally along the length of the probe.

Preferably, the probe includes an outer wall, to which the flexible member is fixed, and the wall has a bending stiffness over at least a portion of its length that is greater than the bending stiffness of the flexible member.

Preferably, the distal end of the pull wire and the distal end of the flexible member are internally fixed in mutually spaced positions to the distal tip of the probe.

Preferably, the probe includes at least one stiffener within the probe, generally parallel to the longitudinal axis thereof, wherein the stiffener has a bending stiffness greater than the bending stiffness of the flexible member. Further preferably, the at least one stiffener has a distal end, which is attached to the proximal end of the flexible member.

Preferably, the at least one stiffener includes a rod made of a resilient material, and the flexible member is formed by flattening a distal portion of the rod.

In a preferred embodiment of the present invention, the probe includes a sheath, fixed to the at least one stiffener, through which sheath the pull wire is drawn.

In another preferred embodiment, the at least one stiffener is movable longitudinally along the length of the probe.

In still another preferred embodiment, the at least one stiffener includes a first stiffener proximal to the flexible member and a second stiffener distal to the flexible member.

In a preferred embodiment of the present invention, when the pull wire is not tensioned, the flexible member assumes a curved resting configuration.

Preferably, the flexible member has a preferred bending plane, such that the bending stiffness of the flexible member is substantially smaller in the preferred bending plane than in an alternative bending plane perpendicular thereto.

In a preferred embodiment of the present invention, the distal end of flexible member is bent to form a curved portion, and wherein the pull wire is attached to the flexible member by threading it through the curved portion, preferably having a spiral shape.

Preferably, the probe contains additional functional elements between the flexible member and the pull wire, and wherein a loop is formed in the pull wire where it is threaded through the curved portion of the flexible member, such that the loop surrounds the additional functional elements.

In a preferred embodiment of the invention, the probe includes one or more spacers, preferably rings, separating the pull wire from the flexible member over at least part of the length of the flexible member.

Preferably, the probe includes a control spindle mounted external to the probe, wherein the proximal end of the pull wire is wound around the control spindle. Preferably, the control spindle is tapered so that diminishing amounts of pull wire are wound onto the spindle for each turn of the spindle as the spindle is rotated in a winding direction.

Preferably, a turn counter indicates the amount of rotation of the control spindle.

In a preferred embodiment of the present invention, the at least one deflection mechanism includes first and second deflection mechanisms, which deflect the probe in respective first and second bending planes thereof. Preferably, the first and second deflection mechanisms include respective first and second flexible members aligned substantially at right angles to one another.

Alternatively, the first and second deflection mechanisms include respective first and second flexible members, which are not aligned at right angles to one another.

Further alternatively, the first and second deflection mechanisms include a common, generally tubular stiffener.

Preferably, the first and second deflection mechanisms include respective first and second pull wires, which are substantially constrained to lie along respective, different longitudinal lines within the probe.

There is further provided, in accordance with a preferred embodiment of the present invention, a method for steering an elongate probe, having a longitudinal axis and a distal tip, including:

fixing an elastic flexible member, having distal and proximal ends and having a predetermined bending stiffness, within the probe generally parallel to the longitudinal axis thereof;

coupling a pull wire at a distal end thereof to the distal end of the flexible member; and

longitudinally tensioning a proximal end of the pull wire to deflect the probe.

Preferably, the method includes fixing a stiffener within the probe, generally parallel to the longitudinal axis thereof, wherein the stiffener has a bending stiffness greater than the bending stiffness of the flexible member. Further preferably, the stiffener includes a rod made of a resilient material, and fixing the flexible member includes flattening a distal portion of the rod to form the flexible member.

In a preferred embodiment, fixing the elastic flexible member includes fixing first and second members having respective preferred bending planes, and tensioning the proximal end of the pull wire includes tensioning one or more wires to deflect the probe in each of the respective bending planes.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic side sectional view of a deflectable catheter in accordance with a preferred embodiment of the invention;

Fig. 2 is an end-on cross-sectional view taken along line II-II in Fig. 1;

Fig. 3A is a side view of a spindle in accordance with a preferred embodiment of the invention;

Fig. 3B is a top view of the spindle of Fig. 3A;

Fig. 4 is a schematic side sectional view of a deflectable catheter in accordance with another preferred embodiment of the invention;

Fig. 5 is a schematic side sectional view of a deflectable catheter having a bending site distant from the distal end of the catheter in accordance with a preferred embodiment of the invention;

Fig. 6 is a schematic side sectional view of a deflectable catheter having a re-locatable bending site in accordance with a preferred embodiment of the invention;

Fig. 7A is a schematic side sectional view of an inwardly biased deflectable catheter in accordance with a preferred embodiment of the invention;

Fig. 7B is a schematic side sectional view of an outwardly biased deflectable catheter in accordance with a preferred embodiment of the invention;

Fig. 8A is a schematic view of a deflectable catheter having a double orthogonal mechanism in accordance with a preferred embodiment of the invention;

Fig. 8B is a schematic view of a deflectable catheter having a double orthogonal mechanism with one tube shaped stiffener in accordance with a preferred embodiment of the invention;

Fig. 9 is an end-on cross-sectional view of a 60° dual pull wire deflection mechanism in accordance with a preferred embodiment of the invention;

Fig. 10A is a schematic, side sectional view of a deflectable catheter, in accordance with another preferred embodiment of the present invention; and

Fig. 10B is a cross-sectional end view of the catheter of Fig. 10A.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 shows a preferred embodiment of a deflectable catheter 32 which comprises a tip deflection mechanism 10, indicated in Fig. 1 by an enclosing dotted line. Except for a part of a pull wire 12 and a control spindle 14, the mechanism is preferably housed inside catheter 32, usually near its distal end. Alternatively, or additionally, modified forms of tip deflection mechanism 10 can be located primarily at other points along the length of the catheter, according to a pre-determined bending site. It should be appreciated that catheter 32 is generally full of apparatus such as wiring, tubes, coils etc.

Referring to Fig. 1, tip deflection mechanism 10 has a bending action which depends upon the flexibility of an elastic flexible member 16, and upon forces applied to flexible member 16 using pull wire 12. To this effect, pull wire 12 is preferably threaded through a curved element 18 at the distal end of flexible member 16. In a preferred embodiment of the present invention, element 18 is a spiral. Alternatively, the curved element comprises a loop, a hook or any other shape which keeps pull wire 12 connected to flexible member 16. In addition, or alternatively, pull wire 12 and flexible member 16 are connected by an adhesive or are welded together.

The proximal end of flexible member 16 preferably protrudes from a stiffener 20 which runs along the length of catheter 32. Stiffener 20 preferably comprises spring steel rod, most preferably about 0.6 mm in diameter, and is considerably stiffer than flexible member 16. Thus, catheter 32 is most yielding at an area parallel to flexible member 16, and tension in pull wire 12 causes catheter 32 to bend primarily at the proximal end of flexible member 16. Nevertheless, stiffener 20 is not so stiff as to interfere with the normal flexibility and maneuverability required of catheter 32. The required maneuverability includes the ability to bend over 360° and pass through narrow passages.

Preferably, stiffener 20 serves as a mooring for flexible member 16. As such, stiffener 20 is connected to flexible member 16 at a point 21 where flexible member 16 protrudes from stiffener 20. Point 21 serves as a pivot about which flexible member 16 begins to bend, as will now be described.

Flexible member 16 has a preferred bending plane conferred upon it, preferably by virtue of it being a substantially flat strip. The strip is seen side-on in Fig. 1, and end-on in Fig. 2 as a straight line 19 at the bottom of spiral 18. The preferred bending plane is coplanar with the plane of spiral 18 and the distal part of pull wire 12. Tension applied to pull wire 12 is transmitted via spiral 18 to flexible member 16 and causes the distal end of flexible member 16

to bend. Thus, flexible member 16 follows a trajectory lying within the preferred bending plane, as indicated in Fig. 1 by a curved arrow 34. Flexible member 16 follows this trajectory because it is held substantially fixed at pivot 21, while being pulled at its distal end at an angle having a substantial perpendicular component to itself. In consequence the trajectory is approximately an arc of a circle centered at pivot point 21 and of radius approximately equal to the length of flexible member 16. Therefore the curvature of trajectory 34, is determined by the length of flexible member 16, and so may be controlled accordingly. When flexible member 16 bends, it presses against apparatus within the catheter and thus exerts force on the catheter wall diametrically opposite flexible member 16 and forces the catheter to bend. Thus, the bending of flexible member 16 causes the catheter to bend, achieving the primary goal of tip deflection mechanism 10. It is noted that the above description is only approximate since flexible member 16 bends not only at pivot 21. Also, stiffener 20 may bend slightly at its distal end along with flexible member 16.

For proper transmission of the bend from flexible member 16 to the catheter, it is necessary to prevent flexible member 16 from slipping. In a preferred embodiment of the invention, the proximal end of the flexible member is fixedly positioned relative to the catheter. This is achieved by connecting pivot point 21 to the catheter wall, or by confining its longitudinal movements. Alternatively, or additionally, there is a high coefficient of friction between flexible member 16 and the apparatus within the catheter and thus flexible member 16 does not slip when exerting force on the catheter. Also, flexible member 16 preferably has enough stiffness to ensure that it does not twist around the center when pulled by pull wire 12. It is noted that repeatable slippage of flexible member 16 does not impede the operation of the deflection mechanism.

To encourage flexible member 16 to bend as just described, the lie of pull wire 12 and the direction of the force it transmits are preferably established by a set of one or more spacers 22. Spacers 22 are attached to flexible member 16 and to pull wire 12, as will now be described.

Pull wire 12 is preferably made of a strong, inelastic and flexible material such as Kevlar, or alternatively, stainless steel or spring steel wire, preferably having a diameter between 0.15 and 0.2 mm. Pull wire 12 runs along the length of catheter 32, and is generally free to run on any line parallel to the axis of catheter 32. However, in the region of flexible member 16, pull wire 12 is preferably constrained to the opposite side of catheter 32 from flexible member 16 so as to achieve leverage over catheter 32. This is achieved using one or

more spacers 22, each of which is attached to pull wire 12 at an attachment 24, and to flexible member 16 at an attachment 26. Attachments 24 and 26 may preferably be made by tying pull wire 12 and flexible member 16, respectively, to spacers 22 with Kevlar thread. Preferably, attachment 26 is diametrically opposite attachment 24. In a preferred embodiment of the invention, when pull wire 12 is pulled the parts of spacers 22 near attachments 24 move with pull wire 12 without substantially moving near attachment 26. Thus the angle between spacers 22 and pull wire 12 changes. Alternatively, attachments 24 surround pull wire 12 such that pull wire 12 is constrained to the opposite side of catheter 32 from flexible member 16, without limiting the longitudinal movement of pull wire 12 relative to attachment 24. Preferably, attachments 24 and 26 are substantially rigid, and they keep spacers 22 generally perpendicular to flexible member 16 and pull wire 12.

In a preferred embodiment of the invention, each of spacers 22 is a ring of a substantially rigid material. Alternatively, each of spacers 22 comprises two substantially rigid half-rings or fibers which are attached together at their ends.

Preferably, tip deflection mechanism 10 is radially fixed relative to the catheter so that the orientation of mechanism 10 does not change relative to the catheter. In some preferred embodiments of the invention, stiffener 20 is constrained as to its position within the cross section of the catheter but can move longitudinally along the catheter. In a preferred embodiment of the invention, one or more rigid loops in which stiffener 20 is situated are connected to the catheter wall. The rigid loops are preferably at the proximal end of the catheter. Alternatively, the stiffener may be constrained by a slot formed in the catheter wall, for example.

Fig. 2 shows an end-on cross-sectional view of the catheter of Fig. 1. As best seen in Fig. 2, a set of one or more cables and/or other interior equipment 28 may run within the catheter. Interior equipment 28 runs along the length of catheter 32, through or past spacers 22. Preferably, pull wire 12 forms, at its distal end, a loop 30, which is threaded through spiral 18 of flexible member 16. Loop 30 circumscribes interior equipment 28 and thus the deflection mechanism functions unencumbered by interior equipment 28. This arrangement of connecting pull wire 12 to flexible member 16, in which loop 30 is threaded through spiral 18, has the advantage of being inherently more reliable and more robust than a glued or welded connection.

If interior equipment 28 forms a relatively firm core occupying a substantial part of the catheter, spacers 22 may be made of a flexible material such as Kevlar. In such a case, spacers 22 may flex under the influence of pull wire 12, either at the points of their attachments or

around their perimeters. In other words, spacers 22 are dragged proximally by pull wire 12, while they are held comparatively stationary on their other side by flexible member 16. Therefore, spacers 22 tilt toward the proximal end of catheter 32 until their tops rest upon interior equipment 28, which prevents their further tilting. Consequently, pull wire 12 is separated from flexible member 16 by the diameter of interior equipment 28. Provided the diameter is sufficiently large, the force exerted by pull wire 12 on flexible member 16 is sufficient to bend flexible member 16 along trajectory 34.

In one preferred embodiment of the invention, tension is applied to pull wire 12 using control spindle 14. When spindle 14 is rotated in one direction, wire 12 is wound onto spindle 14 causing flexible member 16 to bend. On turning spindle 14 in the opposite direction, pull wire 12 is released, and flexible member 16 straightens out due to its inherent springiness. The straightening of flexible member 16 brings deflection mechanism 10 and catheter 32 back towards their original rest position, to the extent that the length of the released length of pull wire 12 allows.

Once in its rest position, catheter 32 tends to remain there, even if spindle 14 is over-rotated and pull wire 12 is allowed to go slack. Thus, although there may be slack in the deflection mechanism when starting to bend catheter 32 from the rest position, there is no inherent dead zone, i.e., the actual degree of bending of flexible member 16 is inherently controllable. Furthermore, there is no inherent backlash in deflection mechanism 10, whatever the position of flexible member 16, i.e., bending advances smoothly in accordance with the tension applied to the pull wire. This is so since there are no inherent sources of significant stiction or friction within deflection mechanism 10.

Reference is made to Fig. 3A and Fig. 3B which show a spindle 114 with a turn counting mechanism and a ratchet. Due to its springiness, the flexible member attempts to return to its rest position, thus pulling on pull wire 12. In order to prevent pull wire 12 from unwinding, the angular position of spindle 114 is preferably maintained by a ratchet 116. Alternatively, the spindle may be maintained by suitable friction, or any other mechanism. Thus, once a degree of bending is achieved, that degree is maintained until spindle 114 is rotated by the user.

In a further embodiment, spindle 114 is used in conjunction with a turn-counting mechanism 118 such as a multi-turn dial used in electronic instrumentation. Using turn counting mechanism 118 the user can monitor the position of spindle 114 up to a small fraction of a turn. Thus, any particular degree of bending of the catheter may be reproduced by the user.

Furthermore, spindle 114 can be tapered so that it has a smaller effective diameter as more wire is wound onto it. This confers finer control just where it is needed, namely where the degree of bending is large and the flexible member is more difficult to control.

In further embodiments of the invention, the catheter bends at a pre-determined site, not necessarily near its tip. Reference is now made to Fig. 4 which illustrates a catheter 132 with a predetermined bending site, in accordance with a preferred embodiment of the invention. As shown in Fig. 4, a flexible member 16 is fixed to the catheter wall 136 at a pre-determined bending site 134. In a preferred embodiment of the invention, flexible member 16 is attached to catheter wall 136 at one end. Alternatively, flexible member 16 is attached to catheter wall 136 at both ends. In another preferred embodiment of the invention, flexible member 16 is attached to catheter wall 136 at one end and to the opposite catheter wall at the other end. Thus, when tension is applied to pull wire 12 the flexible member exerts force on flexible member 16 which presses on the catheter wall and causes the catheter to bend. Instead of using a stiffener, the catheter wall 136 itself is formed so as to be stiff everywhere except at the pre-determined bending site 134. Therefore catheter 132 tends to bend at pre-determined site 134, under the influence of flexible member 16. Thus in this embodiment bending site 134 can be situated at a permanent site anywhere along the length of the catheter including near the distal end.

Another preferred embodiment of a catheter with a predetermined bending site is illustrated in Fig. 5, which shows a deflectable catheter having a bending site distant from the distal end of the catheter. In this embodiment the catheter has two stiffeners 40 and 42 located proximal and distal to the bending site, respectively. A flexible member 44, situated at the bending site, acts as a flexible bridge connecting the two stiffeners. Flexible member 44 is preferably a thin flat section of stiffener material bridging the two stiffeners, and preferably, stiffeners 40 and 42 and flexible member 44 are fabricated in a contiguous manner from a single piece of material.

Preferably, stiffener 40 is fixedly situated within catheter 32. In a preferred embodiment of the invention, stiffeners 40 and 42 are confined by one or more rigid loops which are connected to the catheter wall. Thus, stiffeners 40 and 42 may be moved longitudinally, without being able to move radially within the catheter. In a preferred embodiment of the invention, stiffener 40 is fastened to the catheter wall after it is inserted to the desired depth within the catheter. In a further embodiment of the invention, both stiffeners 40 and 42 are fastened to the catheter wall.

Pull wire 12 is preferably threaded through a loop 46 which in one embodiment is part of flexible member 44. Alternatively, loop 46 connects directly to the proximal end of stiffener 42. As with previously mentioned embodiments, stiffeners 40 and 42 provide the necessary stiffness along the length of the catheter, but are not so stiff as to interfere with the normal flexibility required of the catheter.

An advantage of this embodiment is that the deflection mechanism can be completely pre-fabricated before inserting it into a catheter, and no special features are demanded from the catheter in order to be compatible with the deflection mechanism. Insertion is only a matter of pushing the entire mechanism into the catheter, until stiffener 42 reaches the distal end of the catheter, and securing the deflection mechanism in its place within the catheter.

In another preferred embodiment of the invention the bending site may be re-located while the catheter is in use. Referring back to Fig. 1, a single stiffener 20 passes from the proximal end of the catheter up to the required bending site. Stiffener 20 carries with it a flexible member 16, a pull wire 12, and preferably a set of one or more spacers 22. Distal to the flexible member there is no stiffener as such, rather the catheter wall itself is sufficiently stiff up to the catheter tip, so that the catheter bends only at the pre-determined bending site. Therefore, the whole of the section of the catheter distal to flexible member 16 takes up a position according to the bend applied at the site of flexible member 16.

It should be noted that in this embodiment the whole length of the catheter wall is made sufficiently stiff to maintain correct functioning of the deflection mechanism, wherever re-located. Nevertheless, the catheter still bends at the site of flexible member 16, wherever placed, because that is where a bending moment is applied about pivot point 21, at the junction of flexible member 16 and stiffener 20. The assembly is also more yielding at pivot 21 than along the proximal length of the catheter where the combined stiffness of the catheter wall and the stiffener is the greater.

A further preferred embodiment of the invention is illustrated in Fig. 6, which shows a deflection mechanism which provides the catheter with a re-locatable bending site and an adjustable bending radius. As shown in Fig. 6, a stiffener 52 and a flexible member 50, not attached to one another, are free to be moved independently along the entire length of the catheter. Preferably, flexible member 50 and stiffener 52 are coupled to each other and to the catheter such that they can only move longitudinally along the catheter. The proximal ends of flexible member 50 and stiffener 52, preferably, protrude from the proximal end of the catheter so as to allow for adjusting their positions. Stiffener 52 prevents the catheter from bending

along its length, therefore when flexible member 50 is pulled by pull wire 12, the portion of flexible member 50 distal to the distal end of stiffener 52 bends. The length of this portion can be varied by moving flexible member 50 relative to stiffener 52. Thus, both the bending site and the bending trajectory are selected by positioning stiffener 52 and flexible member 50 appropriately. Preferably before applying force to the pull wire, flexible member 50 and stiffener 52 are fixed in place so as not to move along the catheter instead of bending the catheter.

As with the previous embodiment, the whole length of the catheter wall is preferably sufficiently stiff so that the catheter bends only at the pre-determined bending site. Therefore, the whole distal section of the catheter takes up a position according to the bend applied at the site of flexible member 50.

In a further embodiment of the invention, flexible member 50 lies within stiffener 52 thus minimizing the space within catheter 32, occupied by the tip deflecting mechanism. Flexible member 50 is free to slide within stiffener 52 thus allowing enlarging and shortening of the part of flexible member 50 distal to stiffener 52.

Reference is now made to Figs. 7A and 7B which show deflectable catheters with a non-straight rest position. In some preferred embodiments of the invention the rest position of the catheter is not straight as in Fig. 1, but rather is biased inwardly or outwardly along the preferred bending plane as shown in Figs. 7A and 7B, respectively. The bias is achieved using an elastic flexible member 54 or 56, pre-stressed so as to confer an inherent shape according to a pre-determined bias. Thus, without an applied force, the springiness of the flexible member ensures the catheter returns to the curved rest position, somewhat in the manner of a forged spring.

On comparing Figs. 1, 7A, and 7B it can be seen that for each of the three types of mechanisms (i.e., zero-bias, inward-bias, outward-bias), spacers 22 have different rest positions. In the zero bias mechanism, seen in Fig. 1, spacers 22 are, preferably, all perpendicular to flexible member 16 and pull wire 12. Thus the distance between a pair of attachments 24, joining spacers 22 and pull wires 12, is the same as the distance between a pair of attachments 26, joining spacers 22 and flexible members 16. In contrast, in the inward bias mechanism, seen in Fig. 7A, spacers 22 are, preferably, not all perpendicular to flexible member 22 and pull wire 12, in order to compensate for the resting deflection of the catheter. The distance between a pair of attachments 24, joining spacers 22 and pull wires 12, is smaller than the distance between a pair of attachments 26, joining spacers 22 and flexible members 54. Also

in the outward bias mechanism, seen in Fig. 7B, spacers 22 are, preferably, not all vertical to flexible member 22 and pull wire 12, in order to compensate for the resting deflection of catheter 32. In the outer bias mechanism the distance between a pair of attachments 24, is larger than the distance between a pair of attachments 26.

A significant advantage of an outwardly biased mechanism is that it allows symmetrical bending of the catheter on either side of the straight position shown in Fig. 1.

Further embodiments of the invention facilitate bending of the catheter in more than one direction. Reference is now made to Fig. 8A which shows a catheter with a double deflection mechanism in accordance with a preferred embodiment of the invention. In this embodiment, two complete deflection sets of pull wires 12, stiffeners 20, flexible members 60 and spacers (not shown) are mounted in a catheter 32 independent of each other. In a preferred embodiment of the invention, the sets are mounted orthogonally with respect to each other. Thus, catheter 32 can be bent simultaneously in two mutually perpendicular planes so as to provide a bend lying in any desired plane. In another preferred embodiment of the invention, the distal ends of the stiffeners may be at different depths within the catheter.

In a preferred embodiment of the invention, the two sets may be situated parallel to each other at different depths, thus allowing the user to bend the catheter in an "S" shaped curve.

Preferably, the sets are radially fixed relative to each other and to the catheter. In a preferred embodiment of the invention separators (not shown) are attached to stiffeners 60 of the deflection sets to prevent radial movement of the sets. Alternatively, as shown in Fig. 8B, a single sheath-like cylindrical stiffener 62 replaces stiffeners 20 and maintains a pair of flexible members 64 perpendicular to each other. Flexible members 64 protrude from cylindrical stiffener 62. Preferably both of flexible members 64 are of the same length and an arc of 90° separates between them. Alternatively, flexible members 64 are separated by a different distance or are of different lengths, allowing different radiuses of curvature in different bending directions.

In a preferred embodiment of the invention, the deflection sets are fixed longitudinally relative to each other and are positioned at a fixed point along the catheter. In another preferred embodiment of the invention, the deflection sets may be moved together along the catheter to re-locatable bending sites.

Preferably, the flexible members (either 60 or 64 in Fig. 8A and 8B respectively) do not have preferred bending planes, and are not flat strips as in Fig. 1. Rather flexible members

60 and 64 are preferably circular in cross section so that when one of the pair bends the other will follow without undue resistance. Thus tension applied to one of pull wires 12 bends the flexible member substantially only in the plane shared by it and its associated flexible member. Such tension tends not to influence the degree of bending in the perpendicular plane corresponding to the companion pull wire and its flexible member. In any case, the total tension in the two pull wires determines the degree of bending, and the bend plane is determined based on the amount the pull wires were shortened.

A further preferred embodiment of the invention incorporates a double orthogonal mechanism, such as in Figs. 8A or 8B, in which either or both sets of apparatus have a non-zero bias. If, for example, both sets of apparatus are outwardly biased, then in effect the catheter can be made to bend in any direction relative to the central axis of the catheter.

In other preferred embodiments of the double deflection mechanism, the two sets of apparatus need not be mounted orthogonally with respect to one another. Fig. 9 shows another preferred embodiment of the invention which allows for bending a catheter in more than one plane. Two pull wires 12 are threaded through spiral 18 of a single flexible member forming a dual pull wire mechanism. The planes of the two pull wires are preferably aligned at an angle, such as 60°, with respect to one another. In this embodiment, the bending plane is determined based on the amount pull wires 12 were shortened. It is noted that this embodiment is very simple to implement, and takes up a relatively small section of the inside of the catheter. However this embodiment gives a reduced range of bending planes.

In a preferred embodiment of the invention the maneuverability of the dual pull wire mechanism of Fig. 9 is increased by incorporating within it an outwardly biased flexible member, such as shown in Fig. 7B. Thus, the catheter can be bent on either side of the straight position, and the bending plane can be varied.

Figs. 10A and 10B are schematic, sectional views of a deflectable catheter 32, in accordance with another preferred embodiment of the present invention. Catheter 32 includes a stiffener 82, preferably comprising a stainless steel or spring steel rod, most preferably having a diameter of about 0.6 mm. A portion of stiffener 82 near a distal end 80 of catheter 32 is bent and flattened to form a flexible member 86. Preferably, flexible member 86 is flattened down to a thickness of about 0.10 to 0.15 mm, so that it bends relatively easily in a preferred transverse direction, indicated by an arrow 94 in Fig. 10A, while resisting bending in other directions. A pull wire 84, preferably comprising stainless steel or spring steel wire having a diameter in the range 0.15 to 0.20 mm, runs within catheter 32, generally parallel to stiffener 82. Flexible

member 86 and pull wire 84 are fixed at their distal ends 91 and 90 to an inner surface of a wall 93 of catheter 32, at the catheter's distal end 80, preferably by soldering the flexible member and pull wire in place. The flexible member and the pull wire are thus coupled to one another by means of their mutual connection to wall 93, rather than their being directly attached to one another as in the other preferred embodiments described above.

Catheter 32 generally includes other functional elements on or adjacent to distal end 80, such as wires 28 (Fig. 1), electrodes, a position sensor or other devices known in the art. For simplicity of illustration, these elements are not shown in Figs. 10A and 10B, but it will be appreciated that such elements may be conveniently fixed in between or adjacent to pull wire 84 and flexible member 86.

Preferably, as shown in Figs. 10A and 10B, a sheath 92 surrounds stiffener 82 and pull wire 84. The sheath guides wire 84 along the length of catheter 32 and helps to prevent the wire from tangling or snagging.

Many of the foregoing embodiments of the invention have at least two advantageous constructional features. As previously mentioned, a spiral, loop or other curved element of the flexible member constitute, with a loop at the distal end of the pull wire, a reliable and robust means of connecting the pull wire to the flexible member. In addition, for many of the embodiments, the deflection mechanism can be completely pre-fabricated before inserting it into a catheter. Furthermore, no special features are demanded from the catheter in order for it to be compatible with the deflection mechanism.

It will be appreciated that the preferred embodiments described above are cited by way of example, and the full scope of the invention is limited only by the claims.

## CLAIMS

1. An elongate probe having a longitudinal axis and a distal tip, and comprising at least one deflection mechanism, which comprises:

an elastic flexible member, having distal and proximal ends and having a predetermined bending stiffness, wherein the flexible member is fixed within the probe generally parallel to the longitudinal axis thereof; and

a pull wire having a distal end coupled to the distal end of the flexible member, and a proximal end that is tensioned longitudinally to deflect the probe.

2. A probe according to claim 1, wherein the distal end of the pull wire is fixed to the distal end of the flexible member.

3. A probe according to claim 1, wherein the flexible member is movable longitudinally along the length of the probe.

4. A probe according to claim 1, wherein the probe comprises an outer wall, to which the flexible member is fixed.

5. A probe according to claim 4, wherein the wall has a bending stiffness over at least a portion of its length that is greater than the bending stiffness of the flexible member.

6. A probe according to claim 1, wherein the distal end of the pull wire and the distal end of the flexible member are internally fixed in mutually spaced positions to the distal tip of the probe.

7. A probe according to claim 1, and comprising at least one stiffener within the probe, generally parallel to the longitudinal axis thereof, wherein the stiffener has a bending stiffness greater than the bending stiffness of the flexible member.

8. A probe according to claim 7, wherein the at least one stiffener has a distal end, which is attached to the proximal end of the flexible member.

9. A probe according to claim 8, wherein the at least one stiffener comprises a rod made of a resilient material, and the flexible member is formed by flattening a distal portion of the rod.

10. A probe according to claim 7, and comprising a sheath, fixed to the at least one stiffener, through which sheath the pull wire is drawn.

11. A probe according to claim 7, wherein the at least one stiffener is movable longitudinally along the length of the probe.

12. A probe according to claim 7, wherein the at least one stiffener comprises a first stiffener proximal to the flexible member and a second stiffener distal to the flexible member.

13. A probe according to any of claims 1-12, wherein when the pull wire is not tensioned, the flexible member assumes a curved resting configuration.

14. A probe according to any of claims 1-12, wherein the flexible member has a preferred bending plane, such that the bending stiffness of the flexible member is substantially smaller in the preferred bending plane than in an alternative bending plane perpendicular thereto.

15. A probe according to any of claims 1-12, wherein the distal end of flexible member is bent to form a curved portion, and wherein the pull wire is attached to the flexible member by threading it through the curved portion.

16. A probe according to claim 15, wherein the curved portion has a spiral shape.

17. A probe according to claim 15, wherein the probe contains additional functional elements between the flexible member and the pull wire, and wherein a loop is formed in the pull wire where it is threaded through the curved portion of the flexible member, such that the loop surrounds the additional functional elements.

18. A probe according to any of claims 1-12, comprising one or more spacers separating the pull wire from the flexible member over at least part of the length of the flexible member.

19. A probe according to claim 18, wherein the spacers comprise rings.

20. A probe according to any of claims 1-12, and comprising a control spindle mounted external to the probe, wherein the proximal end of the pull wire is wound around the control spindle.

21. A probe according to claim 20, wherein the control spindle is tapered so that diminishing amounts of pull wire are wound onto the spindle for each turn of the spindle as the spindle is rotated in a winding direction.

22. A probe according to claim 20 or 21, and comprising a turn counter indicating the amount of rotation of the control spindle.

23. A probe according to any of claims 1-12, wherein the at least one deflection mechanism comprises first and second deflection mechanisms, which deflect the probe in respective first and second bending planes thereof.

24. A probe according to claim 23, wherein the first and second deflection mechanisms comprise respective first and second flexible members aligned substantially at right angles to one another.

25. A probe according to claim 24, wherein the first and second deflection mechanisms comprise respective first and second flexible members, which are not aligned at right angles to one another.

26. A probe according to claim 23, wherein the first and second deflection mechanisms comprise respective first and second pull wires, which are substantially constrained to lie along respective, different longitudinal lines within the probe.

27. A probe according to claim 23, wherein the first and second deflection mechanisms comprise a common, generally tubular stiffener.

28. A method for steering an elongate probe, having a longitudinal axis and a distal tip, comprising:

fixing an elastic flexible member, having distal and proximal ends and having a predetermined bending stiffness, within the probe generally parallel to the longitudinal axis thereof; and

coupling a pull wire at a distal end thereof to the distal end of the flexible member; and longitudinally tensioning a proximal end of the pull wire to deflect the probe.

29. A method according to claim 28, and comprising fixing a stiffener within the probe, generally parallel to the longitudinal axis thereof, wherein the stiffener has a bending stiffness greater than the bending stiffness of the flexible member.

30. A method according to claim 29, wherein the stiffener comprises a rod made of a resilient material, and wherein fixing the flexible member comprises flattening a distal portion of the rod to form the flexible member.

31. A method according to any of claims 28-30, wherein fixing the elastic flexible member comprises fixing first and second members having respective preferred bending planes, and wherein tensioning the proximal end of the pull wire comprises tensioning one or more wires to deflect the probe in each of the respective bending planes.

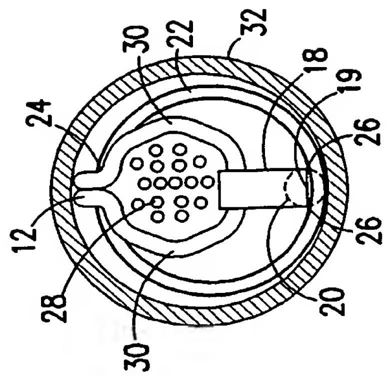
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FIG. 2

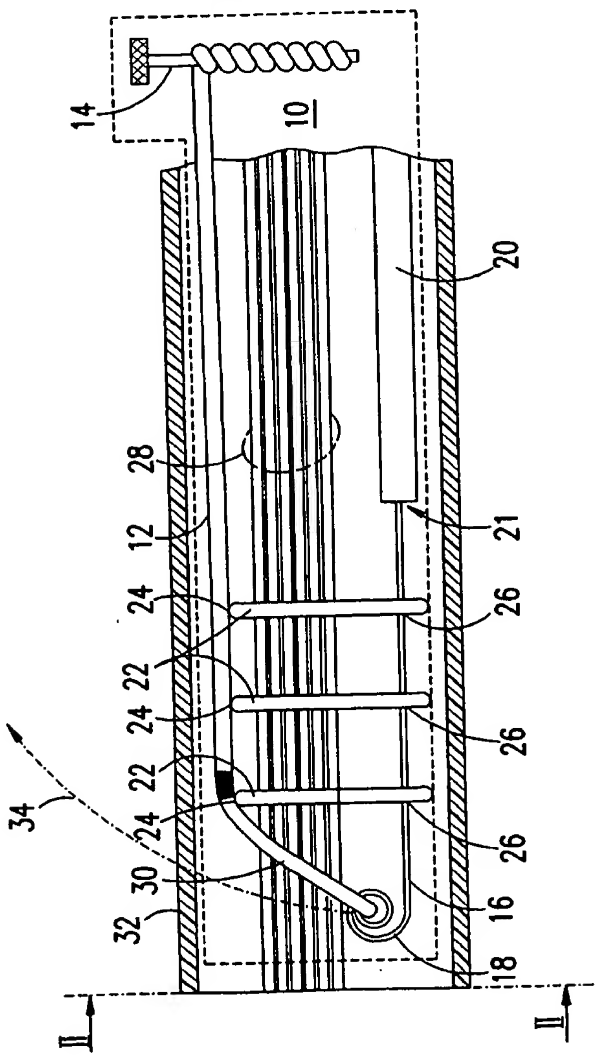
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FIG. 1

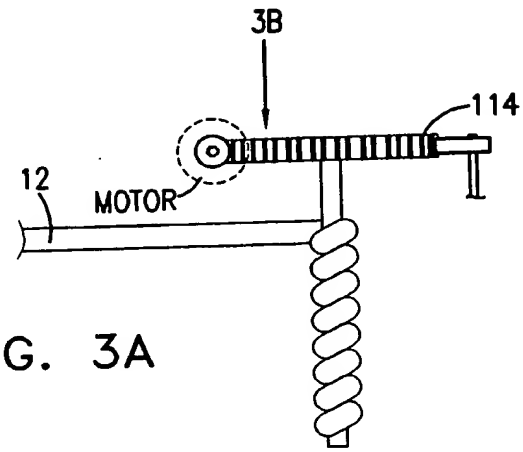



FIG. 3A

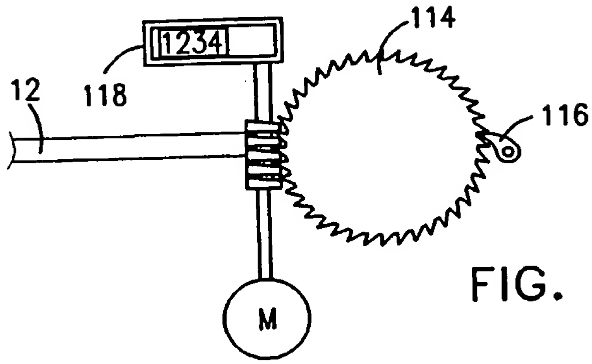
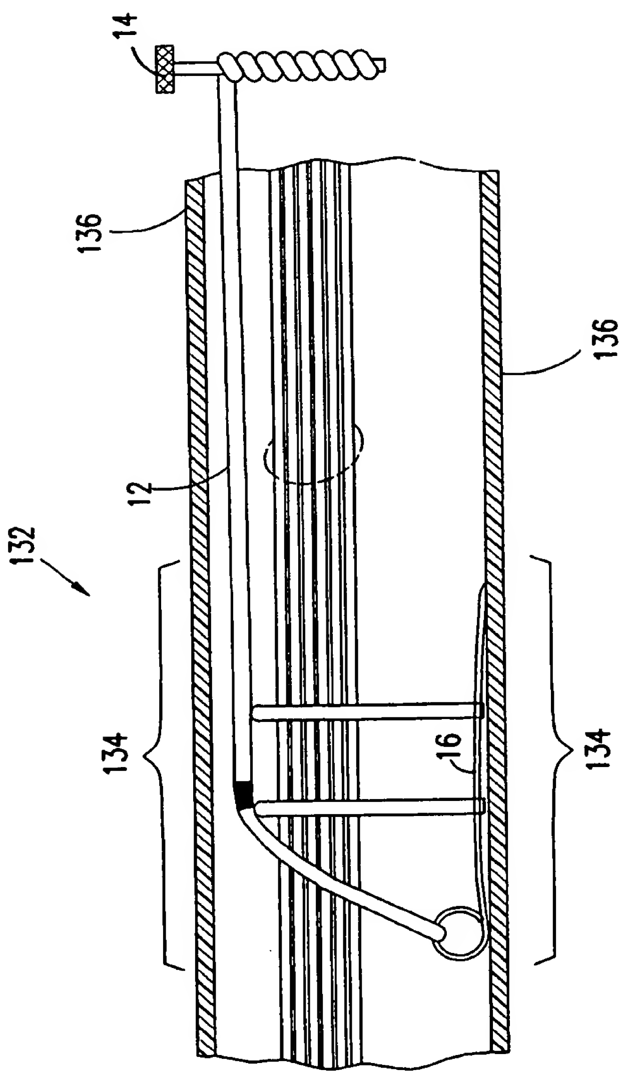



FIG. 3B

FIG. 4



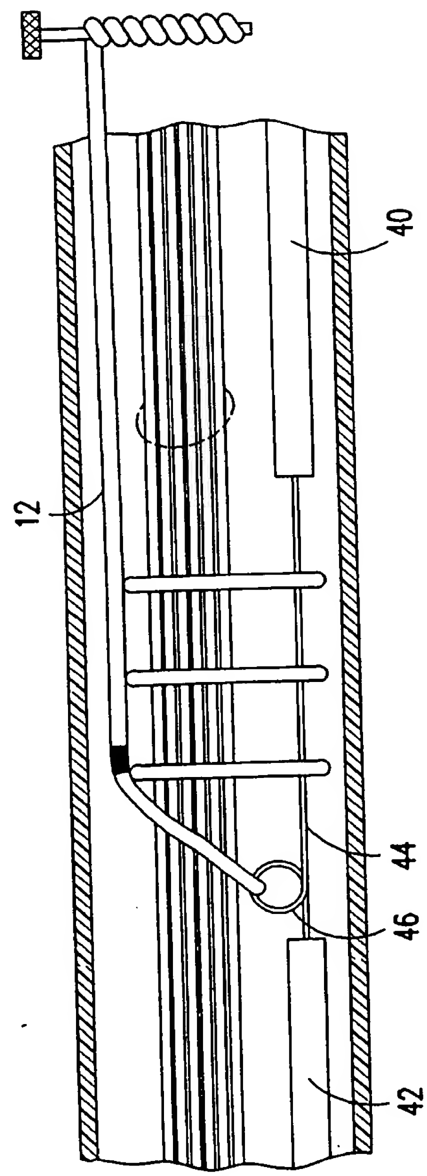



FIG. 5

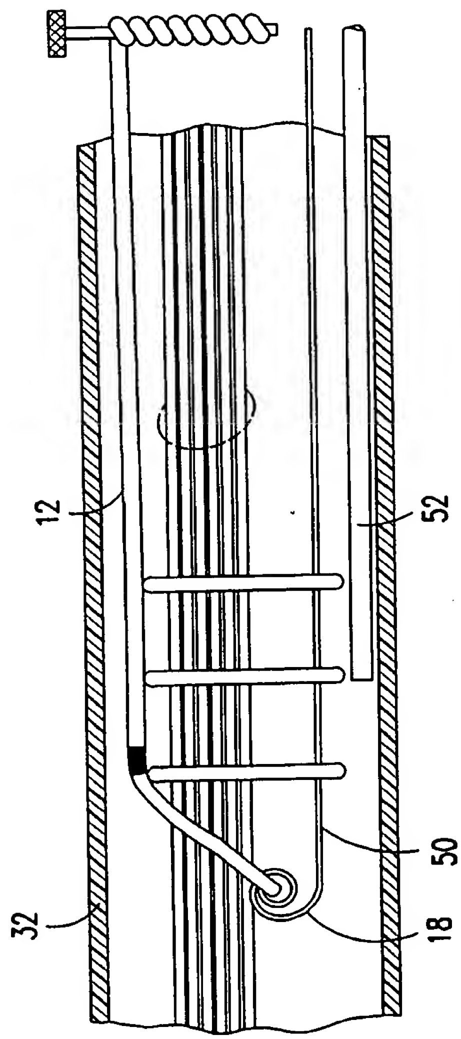



FIG. 6

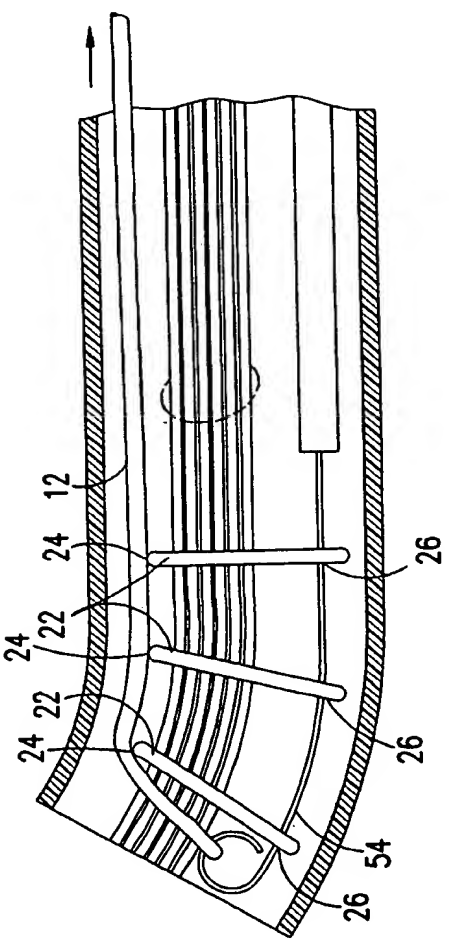



FIG. 7A

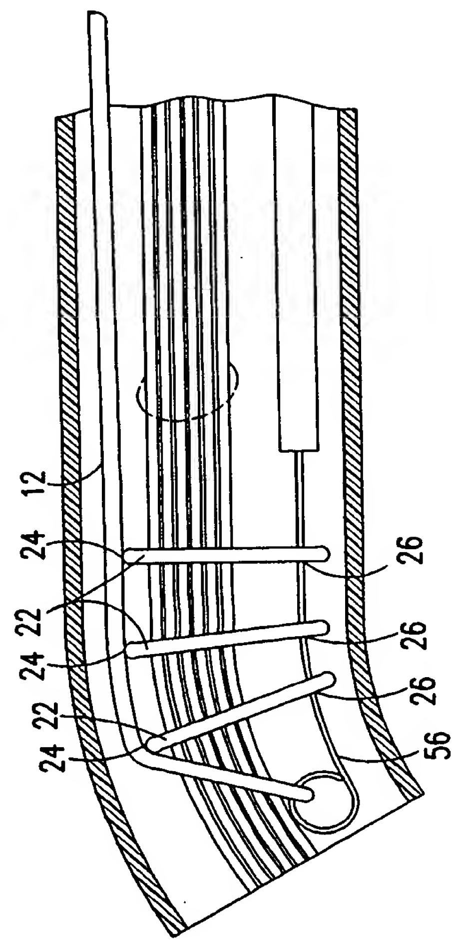



FIG. 7B

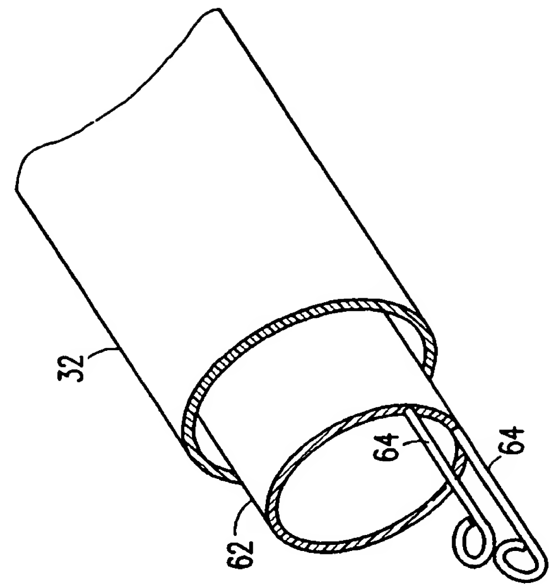



FIG. 8B

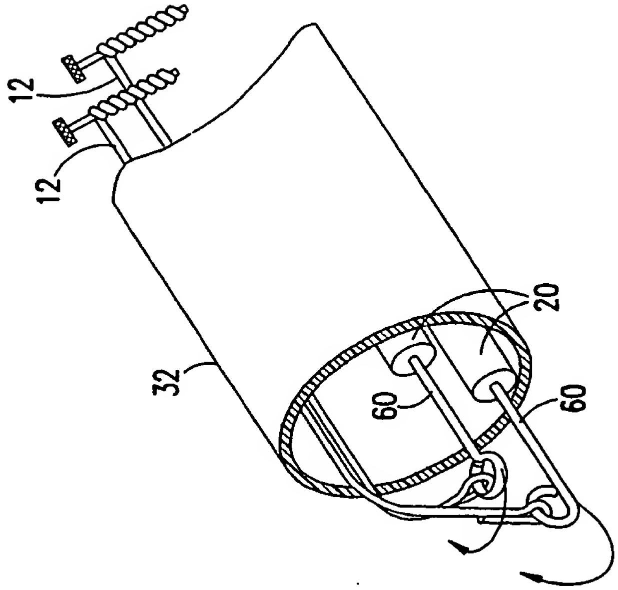



FIG. 8A

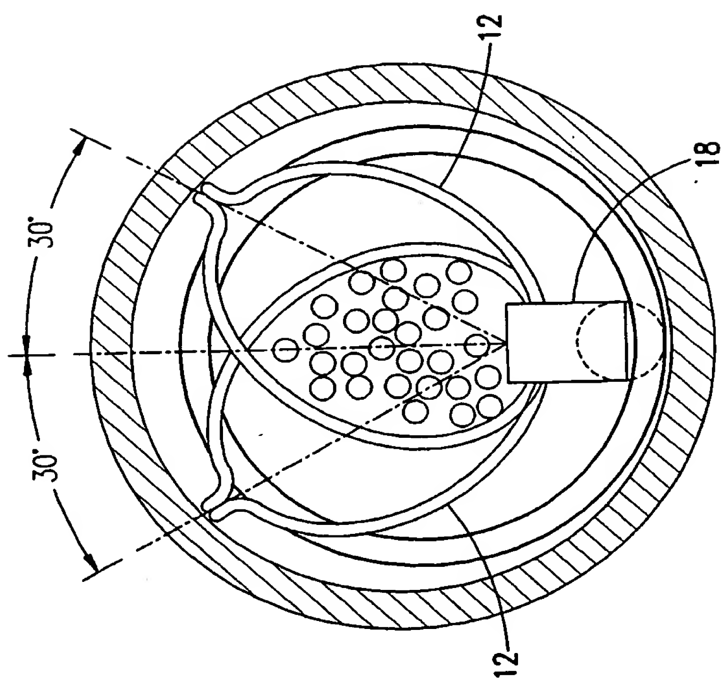



FIG. 9

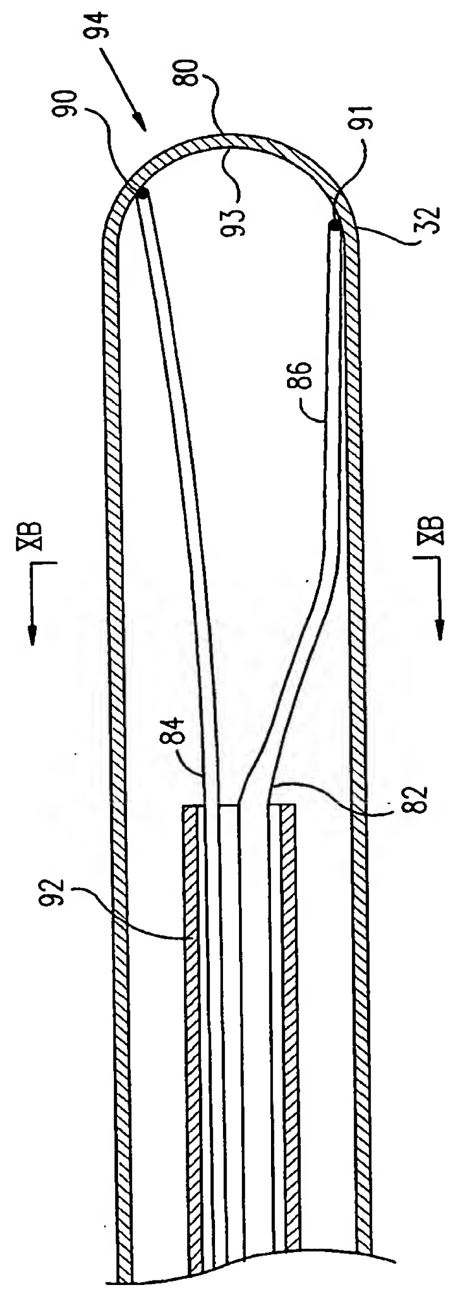



FIG. 10A

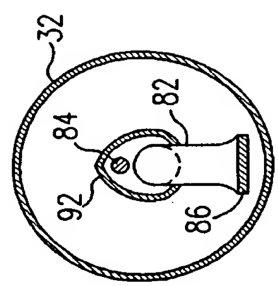



FIG. 10B

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00099

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 1/00, 6/00; A61M 25/00, 37/00
US CL :600/146, 434; 604/95
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/114. 146, 433-435, 585; 604/95, 264, 280-282

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 91/11213 A (LUNDQUIST et al) 08 August 1991, entire document. | 1-7, 10, 11, 14, 20, 23, 26, 28-31 |
| X,P | US 5,656,029 A (IMRAN et al) 12 August 1997, entire document. | 1-7, 18, 19, 28, 31 |
| X | US 5,441,483 A (AVITALL) 15 August 1995, entire document. | 1-7, 10-12, 14, 23, 25, 26, 28, 29, 31 |
| A | US 5,531,687 A (SNOKE et al) 02 July 1996, entire document. | 1-31 |
| A | US 5,328,467 A (EDWARDS et al) 12 July 1994, entire document. | 1-31 |

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

| | |
|---|---|
| Date of the actual completion of the international search<br>29 JUNE 1998 | Date of mailing of the international search report<br>13 AUG 1998 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>LOAN THANH<br>Telephone No. (703) 305-0038 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00099

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 4,758,221 A (JUREIDINI) 19 July 1988, entire document. | 1-31 |
| A | US 5,397,304 A (TRUCKAI) 14 March 1995, entire document. | 1-31 |

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00099

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 22
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.